III. REMARKS

A. Pending Claims

Claims 1-13, 18-19, 21-22, 25-29, 31-54, 57-71 and independent claims 76-81 are pending.

B. Rejections

In the Office Action, the Examiner stated that the recited Tmax is "a functional property of the product claimed and patentability lies with the product itself. Functional properties are viewed as intended use since applicant is limiting the claim to what happens in-vivo after consumption of the product..." The Examiner further states that "the applicant has not provided evidence or claimed the feature that makes it different than the prior art."

This rejection is traversed. It is respectfully submitted that the Examiner's failure to consider the Tmax limitation of the claims (which the Examiner refers to as "intended use" of the formulations) is improper.

Traditionally, an "intended use" in pharmaceutical patent claims would constitute, e.g., the beneficial use of the pharmaceutical in the treatment of a subject, and is typically found in the preamble. This is opposed to a limitation of the formulation itself which is included in the body of the claim. In the field of controlled release pharmaceuticals formulations, it is not uncommon for the formulation to be described and claimed by the particular capability of the formulation in a mode of use, in this case, after oral administration to a human. The characteristic in question, (i.e., Tmax) defines the time period from the oral administration of the dosage form until the time when the greatest concentration of the drug is obtained in the blood plasma of humans. This is not an intended use; rather, this limitation describes release and absorption characteristics of the drug (by virtue of the Tmax limitation) from the claimed dosage form in its environment of use.

A characteristic difference between a controlled release oral dosage form and an immediate release dosage form is, e.g., the rate, concentration levels and time period over which

the drug released from each type of dosage form finds its way into human patients' blood. Similarly, different controlled release oral dosage forms can be differentiated by their release/absorption characteristics. In the present situation, applicants have chosen to utilize the well-understood Tmax characteristic to define the release characteristics of the claimed dosage forms in humans. Rather the Tmax limitation is not an "intended use", but a property of the controlled release formulation.

The Tmax and other pharmacokinetic limitations set forth in the claims are directed to a particular capability of the dosage form when orally administered to humans, and are not directed to the particular reason the dosage forms are administered (which it is respectfully submitted would be the "intended use" of the claimed formulation).

The Examiner's position with respect to "intended use" simply does not find support in the USPTO's treatment of claims in other cases which similarly are directed in part to in-vivo pharmacokinetic characteristics of controlled release drug formulations. Pharmacokinetic parameters, for example, are found in U.S. Patent Nos. 4,894,240; 5,370,879; 5,968,547; 6,399,096; 6,555,581; and 6,660,300 all of which recite claims that recite Tmax limitations. A copy of these patents are attached as Exhibit A for the Examiner's convenience. The Examiner is respectfully reminded that "[a] functional limitation must be evaluated and considered, just like any other limitation of the claim, for what it fairly conveys to a person of ordinary skill in the pertinent art in the context in which it is used. A functional limitation is often used in association with an element, ingredient, or step of a process to define a *particular capability* or purpose that is served by the recited element, ingredient or step." (Emphasis added) MPEP 2173.05(g).

In view of the above, it is respectfully requested that the Examiner reconsider and remove the rejection of the claims based on the "intended use."

Turning now to the rejection apparently based on prior art, it is respectfully submitted that the claims in their present format define characteristics of the release/absorption of the drug from the claimed dosage forms which are patentable because these limitations are respectfully submitted not to be taught or suggested by the prior art relied upon by the Examiner.

In the Office Action, the Examiner acknowledges that "the prior art does not teach the instant Tmax parameter..." (see page 2, lines 7-8 of the Office Action). However, the Examiner later states that "one of ordinary skill in the art has the knowledge to formulate the controlled release dosage form with the instant parameters since the prior art provides the guidance to do so." (see page 2, lines 18-20 of the Office Action). It is respectfully submitted that these statements are contradictory as the Examiner first acknowledges the prior art does not teach the Tmax limitation and shortly thereafter takes the position that the prior art "provides the guidance" to arrive at this Tmax limitation. The Examiner has provided no basis for this "guidance." The Examiner is respectfully reminded that no prior art has been cited, alone or in combination, which fairly teaches or suggests (i) once-a-day controlled release formulations (ii) of the drugs recited in the claims (iii) which provides the claimed Tmax range (e.g., from about 4 hours to about 32 hours in claim 1); or (iv) methods of treatment utilizing the same. Therefore, the Examiner is respectfully requested to withdraw this rejection.

In the Office Action, the Examiner (apparently) incorrectly relies on Chen as a basis for the position that the prior art provides "guidance" for the claimed Tmax ranges. In particular, the Examiner stated that "Chen et al state that 'the dog may not be a good model for predicting relative bioavailability of lovastatin or simvastatin.' This is by no means is [*sic*] a conclusive statement that the dog data is not instructive with respect to humans."

This rejection is traversed as the Chen et al. reference speaks for itself. It is apparent from the Examiner's statement recited above that Chen does not actually hint or suggest the claimed Tmax range, and instead the Examiner is attempting to read that limitation into what Chen actually describes. The Tmax reported in Chen et al. for the sustained and controlled-release formulations after administration to dogs are as follows: SRT8 had a Tmax of 1.8±0.4; SRT14 had a Tmax of 2.3±0.8; CRS8 had a Tmax of 4.0±0.0; and CRS14 had a Tmax of 7.5±1.2. **None of these Tmax's in Chen et al. describe or suggest the Tmax set forth in the claims.**

The point regarding whether dog data is instructive with respect to humans is irrelevant. If dog data is instructive with respect to humans, Chen does not teach or suggest the claimed Tmax ranges in humans in view of the above data. Alternatively, if dog data is not instructive with respect to humans, Chen still does not teach or suggest the claimed Tmax in humans of about 10 to about 32 hours based on the above data. Therefore, the Examiner is respectfully requested to withdraw this rejection. The Examiner's reasoning concerning the Chen et al. reference amounts to the improper use of hindsight.

Accordingly, the Examiner is respectfully requested to withdraw the pending rejections.

IV. Conclusion

It is now believed that the above-referenced rejections have been obviated and withdrawal is respectfully requested. It is believed that all claims are now in condition for allowance.

An early and favorable action is earnestly solicited.

Respectfully submitted,

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